M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: JAN 5 2004

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 1978N-036L

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. CP28

Charles J. Ganley, M.D.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

JAN 5 2004

Peter S. Reichertz
Sonnenschein Nath & Rosenthal
1301 K Street N.W
Suite 600, East Tower
Washington, D.C. 20005

Re: Docket No. 1978N-036L
Comment No. CP28

Dear Mr. Reichertz:

This letter is in response to your citizen petition (CP28), dated June 25, 2003, filed under Docket No. 1978N-036L in the Division of Dockets Management on behalf of C.B. Fleet Company, Inc. The petition requested that FDA modify the January 15, 1985, Tentative Final Monograph on Laxative Drug Products for OTC Human Use (50 FR 2124) to include professional labeling for 2 x 30 mL to 2 x 45 mL dosing of Sodium Phosphates Oral Solution, administered 10-12 hours apart for the purposes of bowel cleansing prior to diagnostic procedures.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the agency is unable to provide a response to the petition at this time. We will respond to your petition as soon as we have made a decision on your request.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Steven Galson, M.D.
Acting Director
Center for Drug Evaluation and Research